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10/723,273	11/25/2003	Michael Barrett	17075-021001 / 0125	8613
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FISH & RICHARDSON, PC			EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/723,273

Applicant(s)

BARRETT ET AL.

Examiner

Nehir Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12.16.2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28-32 is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,11-13,16,18-21 and 23-27 is/are rejected.
- 7) ☒ Claim(s) 3,8-10,14,15,17 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8.16.04; 7.19.04; 3.16.04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims **1, 2, 4, 11, 13, 16, 18-21, 23, 26 and 27** are rejected under 35 U.S.C. 102(e) as being anticipated by Hauschild et al. (US 6,802,846).
3. As to **claim 1**, Hauschild teaches an apparatus that comprises an outer shaft **40** (see **figure 4**) having a distal end; a housing **24** (see **figures 3 and 4**) to the distal end of the shaft and configured to receive the bronchial device; an inner shaft **25** slidably disposed within the outer shaft (see **figure 4**); and a handle **30** (see **figure 2**) adapted to move the outer shaft relative to both the inner shaft and the handle while the inner shaft remains fixed relative to the handle so as to eject the bronchial isolation device from the housing (see **figures 13-15**).
4. As to **claim 2**, Hauschild teaches an apparatus that further comprises a flange **28** coupled to a distal region of the inner shaft and movably disposed in the housing, wherein the flange is adapted to eject the bronchial isolation device from the housing during proximal movement of the outer shaft (see **figures 5-7**).
5. As to **claim 4**, Hauschild teaches an apparatus that further comprises an actuator member **31 and 32** (see **figure 2**) coupled to the handle, wherein movement of the actuation member causes the outer shaft to move to the inner shaft and the handle (see **figures 4-7**).

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6. As to **claim 11**, Hauschild teaches an apparatus that further comprises a sheath **50** (see **figures 2-7**) disposed over a portion of the outer shaft that the outer shaft is slidably disposed within the sheath, the sheath having a proximal end attached to the handle (see **figure 2**).
7. As to **claim 13**, Hauschild teaches an apparatus wherein a portion of the outer slides into the handle when the outer shaft moves in a proximal direction (see **figure 2**).
8. As to **claim 16**, Hauschild teaches an apparatus wherein the outer shaft is configured to be placed through a working channel of a bronchoscope (see **summary of invention**).
9. As to **claim 18**, Hauschild teaches an apparatus that comprises an outer shaft **50** (see **figure 4**) having a distal end; a housing **24** (see **figures 3 and 4**) to the distal end of the shaft and configured to receive the bronchial device; an ejecting member **25** movably disposed in the housing (see **figures 4-7**); and a handle **30** adapted to cause relative movement between the housing and the ejection member so as to eject the bronchial isolation device from the housing, wherein relative movement between the housing and the ejection member is limited to prevent the ejection member from moving substantially outside of the housing (see **figures 5-7**).
10. As to **claim 19**, Hauschild teaches an apparatus that further comprises an inner shaft **40** slidably disposed within the outer shaft, wherein the ejection member is coupled to a distal region of the inner shaft (see **figure 4**).
11. As to **claim 20**, Hauschild teaches an apparatus wherein the outer shaft is configured to move relative to the inner shaft and the handle, while the inner shaft remains fixed relative to the handle (see **figures 4-7**).

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12. As to **claim 21**, Hauschild teaches an apparatus wherein the relative movement between the housing and the ejection member is effected by moving the outer shaft relative to the ejection member.

13. As to **claim 23**, Hauschild teaches an apparatus that comprises a handle **30** (see **figure 2**); an outer shaft **40** movably coupled to the handle (see **figure 2**); an inner shaft **25** slidably disposed within the outer shaft and fixedly coupled the handle (see **figure 2**), the handle adapted to move the outer shaft relative to both the inner shaft and the handle while the inner shaft remains fixed relative to the handle (see **figures 4-7**); and a sheath **50** attached to the handle and disposed over a portion of the outer shaft such that the outer shaft is free to slide within the sheath (see **figure 4**).

14. As to **claim 26**, Hauschild teaches an apparatus that further comprises a housing **24** coupled to the distal end of the outer shaft and configured to receive the bronchial device (see **figure 3**).

15. As to **claim 27**, Hauschild teaches an apparatus wherein the apparatus is adapted for use in a bronchial passageway (see **summary of invention**).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauschild et al. (US 6,802,846).

19. **As to claim 5**, Hauschild substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a rack and pinion system that couples movement of the actuation member to movement of the outer shaft. It would have been obvious matter of design choice to use a rack and pinion system that couples movement of the actuation member to movement of the outer shaft in order to reduce friction, since the applicant has not disclosed that using a rack and pinion system that couples movement of the actuation member to movement of the outer shaft solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the system described in Hauschild.

20. **As to claim 6**, Hauschild substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose an outer shaft that moves at a different rate than the actuating member. It would have been obvious matter of design choice to have an outer shaft that moves at a different rate than the actuating member in order to have better control of the device, since the applicant has not disclosed that having the outer shaft that moves at a different rate than the actuating member solves any stated problem or is for any particular purpose and it appears

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that the invention would perform equally well with the outer shaft moving at the same rate as the actuating member.

21. **As to claim 7**, Hauschild substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose an outer shaft moving about half the distance that the actuation member moves. It would have been obvious matter of design choice to have an outer shaft that moves about half the distance that the actuation member in order to have better control of the device, since the applicant has not disclosed that having the outer shaft that moves about half the distance that the actuation member moves solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the outer shaft moving quarter distance or three-fourth the distance actuation member moves.

22. **Claims 12, 24 and 25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauschild et al. (US 6,802,846) in view of Lenker et al. (US 6,350,278).

23. **As to claims 12, 24 and 25**, Hauschild substantially discloses the claimed invention; see rejection of claims 1 and 23 above, but does not disclose the sheath comprising a lubricous material that comprises polyamide, Teflon doped polyamide or polyetheretherketone. Leanker teaches an apparatus that does provide a sheath comprising a lubricous material that comprises polyamide, Teflon doped polyamide or polyetheretherketone (**see column 8 lines 25-40**).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Hauschild's invention by providing a sheath comprising a lubricous material that comprises polyamide, Teflon doped polyamide or polyetheretherketone as taught by Lenker in order to reduce the friction and make it easier to move for the user.

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Allowable Subject Matter

24. Claims **28-32** are allowed. The prior art does not teach or suggest a method of deploying a bronchial device in a bronchial passageway in a patient's lung; advancing the delivery catheter into the patient's lung with the housing carrying the bronchial device until the housing is positioned in the bronchial passageway.

25. Claims **3, 8-10, 14, 15, 17 and 22** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach housing that has limited range of travel relative to the flange such that the flange does not move substantially outside of the housing.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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10/29/07